

**On-Site Evaluation of the US EPA Region 4
Drinking Water Laboratory Certification Program**

by the

**Office of Ground Water and Drinking Water
Technical Support Center**

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U. S. ENVIRONMENTAL PROTECTION AGENCY

Cincinnati, Ohio 45268

Introduction

The “Manual for the Certification of Laboratories Analyzing Drinking Water” requires the Office of Ground Water and Drinking Water (OGWDW) to “review the Regional drinking water certification programs annually and evaluate the resources and personnel available in each Region to carry out the certification program.” Paper reviews in the form of questionnaires are done annually with on-site reviews conducted triennially. Jennifer Best and Michella Karapondo of the Technical Support Center (TSC) performed a Quality System Assessment (QSA) of the Region 4 Drinking Water Laboratory Certification Program on November 3-5, 2008 at the Region 4 laboratory in Athens, GA. The on-site evaluation is conducted to assess the adherence of the EPA Regional Certification Authority to the requirements of the “Manual for the Certification of Laboratories Analyzing Drinking Water,” Chapters I – III, Fifth Edition, EPA 815-R-05-004, 2005, and any subsequent Supplements to this Manual. The QSA included a review of documents and discussions with Marilyn Maycock, Stephanie Foster Wimpey, and Charlie Appleby, staff members of the Region 4 Laboratory Certification Program.

Where the OGWDW evaluation team has become aware of a particular action taken (or planned) by Region 4 subsequent to the on-site evaluation, that action (or plan) is noted below as a Region 4 response.

Quality and Timeliness of State Laboratory Audits

Principal State Laboratory (PSL) audits for Chemistry, Microbiology and Radiochemistry are to be conducted on a 3-year cycle as described in the “Manual for the Certification of the Laboratories Analyzing Drinking Water” (Laboratory Certification Manual or LCM). Along with PSL audits, assessment of the state laboratory certification program should be performed, as outlined in Chapter III of the LCM. The chart below gives the last dates audits were performed of the PSLs and drinking water laboratory certification programs for the states in Region 4:

STATE	LAST AUDIT OF PRINCIPAL STATE CHEM LAB	LAST AUDIT OF PRINCIPAL STATE MICRO LAB	LAST AUDIT OF PRINCIPAL STATE RAD LAB	LAST DW LAB CERT PROGRAM AUDIT
AL	June 2005	June 2005	November 2007	November 2007
Cherokee Nation	March 2007 (most contracted out)	March 2007	N/A	N/A
FL	Performed by NYDOH (TNI) April 2005	Performed by NYDOH (TNI) March 2007	December 2008	July 2008; as a part of the TNI AA evaluations
GA	October 2006	October 2006	December 2005	October 2006
KY	September 2005	November 2005	No Rad capacity	November 2005
MS	May 2006	May 2006	April 2008	May 2006
NC	March 2007	April 2007	June 2008	March 2007
SC	January 2005	January 2005	December 2007	January 2005
TN	August 2005	August 2005	September 2008	August 2005

The Region 4 certification program is current on all state principle laboratory (PSL) audits as well as certification program reviews, which is a significant accomplishment due to the large number of states within Region 4. In addition to conducting the PSL and laboratory certification program reviews, the Region 4 laboratory certification program staff members have been participating in the radiochemistry PSL audits conducted by an OGWDW contractor.

Region 4 is to be commended for maintaining highly qualified staff members with appropriate technical expertise on the laboratory certification team. The technical nature of the laboratory certification team serves both to strengthen the certification program and to protect public health. Because the Region 4 staff members are familiar with the methods being performed, not only can they serve as auditors, but they are also able to serve as educators to the laboratories that they oversee. This strengthens the certification program as the state laboratory staff can work with Region 4 to resolve any issues or deficiencies that may occur. In addition, based on the reports reviewed by the OGWDW evaluation team, the Region 4 COs have an in depth understanding of the methods and laboratory practices and are able to identify deficiencies that the state laboratory may have.

Reviews of State Certification Programs

On an annual basis, TSC sends a questionnaire to all of the Regional Laboratory Certification Program Managers (LCPMs) regarding the status of the certification program in the states within their Region. Ms. Maycock, the Region 4 Laboratory Certification Program Manager, forwards this questionnaire to the states in Region 4. This questionnaire serves as an annual program review for the states in Region 4, while on-site evaluations of the state programs, conducted by the Region 4 laboratory certification program staff, occur on a triennial basis. The procedure for conducting these program reviews is outlined in the Region 4 SOP #001 “Quality System Assessment of the Region 4 States responsible for Drinking Water Laboratory Certification”. As with the on-site evaluations of PSLs, the Region 4 laboratory certification program has kept on schedule, and has been conducting program reviews every three years.

The OGWDW evaluation team reviewed the Region 4 SOP and noted some inconsistencies in the dates on some of the pages, indicating that some pages within the document had been updated. If an individual page of the SOP is updated, a new version of the SOP should be issued, and the date updated on all pages of the SOP. In addition to inconsistent dates in the document, there were some other minor errors that need to be corrected, such as the removal of the reference to NIST’s involvement in the PT program, and the Lab Code database being maintained in ORD (it is maintained by OGWDW/TSC). The Region 4 certification team should correct these minor inconsistencies and issue a new version of the SOP.

In addition, the evaluation team noted that the Region 4 SOP would benefit from additional detail about how Region 4 conducts state program reviews (i.e.: what documents are reviewed, what personnel are interviewed, is the CO staffing appropriate, is CO training adequate?). In adding those details, OGWDW suggests that Region 4 consider preparing two SOPs: one that covers the PSL audits and one that addresses the state certification program reviews. OGWDW

has SOPs from other Regions that have done this, and can share them with the Region 4 laboratory certification staff to assist them in preparing these documents.

REGION 4 RESPONSE:

A SEPARATE SOP FOR THE STATE CERTIFICATION PROGRAM REVIEWS WILL BE PREPARED. Region 4 would like to see the SOPs from the other Regions to assist us in our preparation of the new SOP.

Regional Certification Program Files

Files from all of the states and tribes within Region 4 were reviewed by the OGWDW evaluation team. Because Region 4 has a large program, covering eight states, they have a voluminous amount of files, some going back more than the last ten years. The OGWDW evaluation team suggests that Region 4 review what they currently need to keep on hand (OGWDW recommends only the last two onsite evaluations) and archive the rest of the files in records storage.

In several instances, the Region 4 laboratory certification files were incomplete. In some instances, the OGWDW evaluation team was unclear as to what had occurred, and had to interview the Region 4 laboratory certification program staff to obtain additional information. For instance, the file for the radiochemistry laboratory for Alabama Department of Environmental Management (ADEM) contained only the draft audit report from the OGWDW contractor, which recommended the lab be “not certified” for all radiochemistry methods. However, through discussion with Region 4 that occurred both before the review by the OGWDW evaluation team and discussions that occurred while the team was visiting Region 4, the OGWDW evaluation team was made aware that Region 4 has been working with ADEM and that Region 4 has granted ADEM provisional certification while they address the findings of the audit report. The OGWDW evaluation team recommends that the file contain documentation of the work ADEM is doing to address the findings of the audit report, as well as Region 4’s final certification decision for the radiochemistry methods at ADEM. Any and all communication with the states should be documented to ensure that Agency records are complete.

The OGWDW evaluation team also noted other deficiencies in the files, e.g. in several files corrective actions/follow-ups from the on-site evaluations were missing and notes/checklists from on-site evaluations were not included in all files. It was difficult for the OGWDW evaluation team to understand whether the on-site evaluations were followed up on, and if so, if the deviations were corrected. The OGWDW evaluation team suggests that Region 4 include all pertinent communication with the states in the files. Documentation of communication between the Regions and states becomes important should any regulatory or certification status questions arise. This would serve to demonstrate that Region 4 had communicated with states and PSLs regarding any problems/issues that may arise and serve to document any misunderstandings that may occur. To simplify the filing of all of these documents, the Region 4 laboratory certification team should consider splitting the files into two types of files: one file for PSL evaluations and one file for laboratory certification program matters for each state.

REGION 4 RESPONSE:

THIS WILL BE IMPLEMENTED FOR ALL FUTURE FILES

The OGWDW evaluation team also suggests that the Region 4 laboratory certification staff include all files pertaining to their participation in the TNI evaluation of the FL Accreditation program, including a copy of the AB evaluation report, in the FL files. Region 4 should also document that, based on the TNI evaluation and any other factors the Region deems appropriate, Region 4 is satisfied that FL is operating an acceptable program (i.e., such that Region 4 deems the program as satisfying the primacy requirements of 40 CFR 142.10(b)(3). In addition, the Region 4 laboratory certification staff should continue to request a copy of the FL PSL audit report and certificates from the AB performing the audit. These documents should also be included in the FL files to the extent that they are used as the basis for Region 4's determination that the FL PSL is satisfying the primacy requirements of 40 CFR 142.10(b)(4).

The Region 4 laboratory certification team has current files demonstrating the proficiency testing (PT) results for each PSL in the region. Region 4, and in particular Ms. Foster Wimpey, are to be commended for the manner in which all of the PSL PT results are maintained. The PT results are filed by year with a spread sheet showing whether the laboratory passed or failed the PT for each contaminant. In addition, the results are color coded to indicate which analytes are analyzed by a contracted laboratory. This is the best system that the OGWDW evaluation team has seen to date for keeping track of PT results. In addition, as far as the evaluation team is aware, Region 4 is the only state keeping track on a yearly basis as to which analytes the state PSLs are contracting out. The evaluation team has requested permission from the Region 4 laboratory evaluation staff to share this system with other EPA Regional personnel, and suggest that other Regions consider this innovative filing system.

In addition to the PT results, the Region 4 laboratory certification staff issue certification letters to each PSL each year after passing PT results are received. These letters were appropriately placed with each of the state files, and were up to date for each of the states within Region 4. The OGWDW evaluation team suggested that Region 4 add expiration dates to these letters in order to ensure that the states (and anyone seeing the PSL certificate) are clear as to how long their certification is valid.

REGION 4 RESPONSE: THIS HAS BEEN CORRECTED, A COPY OF A CORRECTED PT LETTER IS INCLUDED IN UPDATED VERSION OF SOP, AND AN UPDATED VERSION OF A PT LETTER FROM THIS YEAR IS ATTACHED.

Communications with State Counterparts

The Region 4 laboratory holds an annual meeting with the state certification program personnel from all of the states within the Region. The Region 4 laboratory is to be commended for continued support of this meeting, which includes Region 4's commitment to funding one individual's travel from each state to attend the meeting. The OGWDW evaluation team notes that this support from the Region 4 laboratory serves to foster an environment of communication and respect, which serve to strengthen the certification programs of the states.

The Region 4 annual meeting agenda is well thought out, and appears to contain much information that is very relevant to the states. For example, for the 2008 meeting, Region 4 included a session about Polymerase Chain Reaction (PCR), which is something that the states may be hearing more about in the future of microbiological methods. In addition, the 2008 meeting included a session about radiochemistry methods, information that is very timely and of interest amongst the Region 4 laboratory and state personnel.

Resources

Region 4 is to be commended for doing a tremendous job in supporting the drinking water laboratory certification program through both personnel and travel resources. The OGWDW evaluation team noted that for the PSL evaluations, the number of Region 4 auditors was adequate in all cases, and OGWDW appreciates this investment by Region 4. We believe this support encourages the maintenance of a strong laboratory certification program, both within the Region and the state programs.

The OGWDW evaluation team notes that the Region 4 laboratory certification staff currently consists of: Marilyn Maycock, program manager and microbiologist, Charlie Appleby, chemist, Ray Terhune, chemist, Denise Goddard, chemist, and Stephanie Foster Wimpey, chemist. With Ms. Maycock currently serving as the program manager and sole microbiology CO, we are concerned that this could become a resource issue, particularly given the number of audits to be conducted in 2009. Based on the volume of work, the OGWDW evaluation team is again recommending (see also our recommendation in the 2005 report) that the Region 4 laboratory certification program would benefit from having another microbiologist CO on the laboratory certification team.

FINDINGS:

- The Region 4 laboratory certification team is encouraged to go through all state files and archive any files no longer needed on-site to allow for better records management.

REGION 4 RESPONSE:

ALL OLDER FILES HAVE BEEN ARCHIVED

- Region 4 should include any relevant documents regarding the evaluation of Florida's TNI program and accreditation of the FL PSLs in a central (FL) file, to support Region 4's assessment of the FL program and FL PSLs.
- The Region 4 laboratory certification program should ensure that all files are complete. All actions regarding state certification programs and laboratories should be documented in the files. In particular, all decisions involving certification status change should be thoroughly documented.
- The OGWDW evaluation team recommends that another microbiology CO be added to the Region 4 laboratory certification team.

ACTION ITEMS:

- Minor inconsistencies need to be corrected in the Region 4 SOP #0001. Please forward copies to Judy Brisbin when completed.

REGION 4 RESPONSE: CHANGES HAVE BEEN MADE AND A CURRENT COPY OF SOP FORWARDED TO JUDY BRISBIN

Submitted February 17, 2009

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